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9 UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
10 SAN JOSE DIVISION  
11

12 UNITED STATES OF AMERICA,

13 Plaintiff,

14 v.

15 RAMESH "SUNNY" BALWANI,

16 Defendant.

Case No. CR-18-00258-EJD

**RAMESH "SUNNY" BALWANI'S  
REPLY IN SUPPORT OF MOTION TO  
ALLOW CROSS-EXAMINATION  
RELATING TO DR. ADAM  
ROSENDORFF'S  
POST-THERANOS EMPLOYMENT**

**Date: April 19, 2022**

**Time: 8:30 a.m.**

**CTRM.: 4, 5th Floor**

**Hon. Edward J. Davila**

1     **I.     INTRODUCTION**

2             While busy arguing about whether Dr. Rosendorff actually is biased, the government  
3     misses the issue before the Court: whether Mr. Balwani may probe Dr. Rosendorff’s potential  
4     bias during cross examination in the first place. Whether Dr. Rosendorff is actually biased is a  
5     question for the jury.

6             The response also overlooks the multifaceted nature of Dr. Rosendorff’s bias. It focuses  
7     on certain possible sources of bias—like fear of sanctions in any particular investigation—to the  
8     exclusion of others—like Dr. Rosendorff’s desire to protect his reputation in the lab industry  
9     through blaming Mr. Balwani and others. The three investigations raised in Mr. Balwani’s motion  
10    could reasonably motivate Dr. Rosendorff to deflect blame away from himself, and the jury  
11    should be permitted to consider that motive in evaluating his credibility.

12    **II.    ARGUMENT**

13           **A.     The Government Misstates The Facts Bearing On Dr. Rosendorff’s Bias.**

14           The government’s response presents a one-sided version of events that downplays the  
15    potential effects on Dr. Rosendorff’s testimony. As described below, the jury should decide what  
16    weight to give the evidence of bias. But should this Court find it necessary to weigh that evidence  
17    itself, it should reject the government’s skewed facts.

18           *Invitae*. As Mr. Balwani’s motion explained, Dr. Rosendorff presided over lab errors at  
19    Invitae that resulted in his departure and the retesting of 50,000 patients, and Invitae is now the  
20    subject of a federal investigation. Dkt. 1401 at 1–2. The government tries to cast doubt on these  
21    events as a source of witness bias, but its factual claims are conspicuously thin. For example, the  
22    government asserts that its investigation into Invitae “may not even be related” to  
23    Dr. Rosendorff’s role, Dkt. 1405 at 5, but of course only the government knows the answer to that  
24    question. And the government claims that it “has no documents from the time period of

1 Dr. Rosendorff's employment at Invitae," Dkt. 1405 at 4 (quoting Dkt. 1401-3 at 271), but it has  
 2 refused to produce the subpoena it served on Invitae, Dkt. 1401-3 at 271. Nor does the  
 3 government's vague statement rule out the possibility that the subpoena covers the time of  
 4 Dr. Rosendorff's employment—but that Invitae simply has yet to respond to the subpoena. Given  
 5 how easily the government could clarify that the ongoing investigation into Invitae does not  
 6 concern Dr. Rosendorff, its failure to do so is telling.

7 The government also tries to downplay the severity of the problems at Invitae. *See*  
 8 Dkt. 1405 at 4–5. But the 50,000-patient headcount was “likely a record high for such an error” in  
 9 the industry. Dkt. 1077-5 at 2 (Robert Michel, “50,000 Patients to Retest After Invitae Finds  
 10 Errors,” *The Dark Report* (Aug. 28, 2017)). Contemporaneous industry reports described it as “a  
 11 significant event for the clinical laboratory profession”; explained that inspectors would view it as  
 12 “extraordinary for any laboratory to have performed inaccurate tests on 50,000 patients over 11  
 13 months,” and predicted that “[p]athologists and lab administrators will watch closely to see if  
 14 officials inspect the Invitae lab.” *Id.* at 3–4.

15 ***uBiome.*** Federal scrutiny also turned to uBiome, where Dr. Rosendorff served as lab  
 16 director under founders who have since been indicted for fraud. Dkt. 1401 at 2. The government's  
 17 response on uBiome relies entirely on its characterization of the criminal charges there as cabined  
 18 to a “health-care *billing*-related fraud scheme.” Dkt. 1405 at 6. But no matter how emphatically  
 19 the government says this was about “billing,” *id.* at 3, 6, the Court can see for itself: the  
 20 allegations in the uBiome case touch on fraud that came squarely within the lab director's  
 21 purview, like performing tests on patient samples that “had not been validated under CLIA  
 22 standards” and “manipulating the dates of service” on lab tests. Indictment at ¶ 38, *United States*  
 23 *v. Apte*, No. 3:21-cr-00116-CRB (N.D. Cal. filed Mar. 18, 2021), ECF No. 1. The indictment also  
 24 alleges that uBiome validated and launched allegedly fraudulent products during Dr. Rosendorff's

1 time there, *id.* at ¶¶ 20, 44, and uBiome marketed lab tests that were not “medically necessary,”  
 2 *id.* at ¶ 38. Indeed, uBiome’s laboratory directors are expressly discussed in the indictment: The  
 3 two directors in place after Dr. Rosendorff expressed concerns about the practices they  
 4 encountered—and then “left their roles shortly thereafter.” *Id.* at ¶ 41. The uBiome founders  
 5 likely could not have pulled off their alleged fraud, including allegedly falsifying the dates of  
 6 tests, without help from their lab.

7 The government insists that Dr. Rosendorff was unaware of fraudulent practices at  
 8 uBiome. Dkt. 1405 at 3–4. But a jury could easily disbelieve him. The laboratory director before  
 9 Dr. Rosendorff knew, and he quit over it. *Id.* (citing 10/05/2021 Holmes Trial Tr. at 2566). The  
 10 two laboratory directors in place after him knew, and they too left. *Apte* Indictment at 10–11.  
 11 There is therefore good reason to believe that Dr. Rosendorff similarly knew of and oversaw  
 12 those same concerning, allegedly fraudulent practices.

13 There is also good reason to believe that Dr. Rosendorff is concerned about the  
 14 reputational effects of being tied to the investigations that plague his workplaces. The government  
 15 points the Court to Dr. Rosendorff’s LinkedIn page, Dkt. 1405 at 2 n.1, where he conspicuously  
 16 makes no mention of uBiome, *see* <https://www.linkedin.com/in/adam-rosendorff-5473a616>.

17 ***PerkinElmer.*** The government does not dispute that Dr. Rosendorff himself was served  
 18 with three immediate-jeopardy notices pursuant to a Center for Medicare & Medicaid Services  
 19 (“CMS”) investigation into PerkinElmer. Dkt. 1401 at 2. Instead, it tries to downplay the  
 20 investigation at PerkinElmer as “mostly related to ‘document review and review of the L.I.S.’  
 21 systems,” and by explaining that CMS has “declined to impose sanctions” because PerkinElmer  
 22 “corrected the identified deficiencies.” Dkt. 1405 at 4 (quoting 10/05/2021 Holmes Trial Tr. at  
 23 2719). Dr. Rosendorff’s description of the scope of the investigation is exceptionally vague;  
 24 virtually all lab investigations involve document and database review. It also defies belief. As

1 Dr. Rosendorff well knows, the investigation looked specifically at whether *Dr. Rosendorff*  
 2 “failed to ensure quality assurance activities were established and maintained by the laboratory to  
 3 assure the quality of services provided, and to identify failures in quality as they occur” and  
 4 whether he “failed to ensure the laboratory staff demonstrated competency prior to reporting  
 5 patient test results.” California Dep’t of Pub. Health, *Statement of Deficiencies and Plan of*  
 6 *Correction* at 37 (Apr. 22, 2021).<sup>1</sup>

7 Despite the government’s representations about the scope and conclusion of the  
 8 PerkinElmer investigation, the jury could conclude that Dr. Rosendorff is motivated to give  
 9 biased testimony to deflect attention and protect his professional reputation. Indeed, industry  
 10 reaction to the events at PerkinElmer was heightened in part *because* the government eventually  
 11 cleared the lab: “lab experts” described “clear[] contradict[ions]” between the investigation’s  
 12 conclusions and the fact that PerkinElmer “failed to correct the deficiencies for at least nine  
 13 months ... as they struggled to bring the lab into compliance while continuing to process patient  
 14 samples.” *CBS13*, “Lab Experts Criticize State’s Response to Risk of ‘Serious Injury, Harm or  
 15 Death’ at CA COVID Testing Lab” (Dec. 5, 2021).<sup>2</sup>

16 **B. A Jury “Might Reasonably” Question Dr. Rosendorff’s Bias.**

17 The foregoing evidence more than suffices to put these bias issues to the jury. In order to  
 18 do so, Mr. Balwani need only show that a potential source of bias “‘might reasonably’ lead a jury  
 19 to ‘question[] the witness’s reliability or credibility.’” *Gibbs v. Covello*, 996 F.3d 596, 601 (9th  
 20 Cir. 2021) (alteration in original) (quoting *Fowler v. Sacramento Cty. Sheriff’s Dep’t*, 421 F.3d  
 21 1027, 1036 (9th Cir. 2005)), *cert denied*, 142 S. Ct. 285 (2021), and 142 S. Ct. 453 (2021);

22  
 23 <sup>1</sup>[https://www.cdph.ca.gov/Programs/OSPHLD/LFS/CDPH%20Document%20Library/VBL/Complaint/State2567%20Complaint%20Investigation%20CDPH%20Branch%20Lab%2004222021%20\(002\)\\_Redacted.pdf](https://www.cdph.ca.gov/Programs/OSPHLD/LFS/CDPH%20Document%20Library/VBL/Complaint/State2567%20Complaint%20Investigation%20CDPH%20Branch%20Lab%2004222021%20(002)_Redacted.pdf).

24 <sup>2</sup> <https://gooddaysacramento.cbslocal.com/2021/12/05/experts-criticize-cdph-california-covid-testing-lab-investigation/>.

1 accord *Delaware v. Van Arsdall*, 475 U.S. 673, 679–80 (1986). And once that low “might  
 2 reasonably” bar is met, the Ninth Circuit has held that further weighing of the evidence is the  
 3 province of the jury. The jury gets to decide, for example, whether enough time has passed to  
 4 quell any likely bias or whether incidents are similar enough to indicate witness fabrication. *See*  
 5 *Fowler*, 421 F.3d at 1040–41 (reversing denial of habeas in light of “objectively unreasonable”  
 6 exclusion of bias inquiry based on trial court’s view of evidence that a “jury might reasonably  
 7 have questioned”); *Greatbreaks v. United States*, 211 F.2d 674, 676–77 (9th Cir. 1954) (reversing  
 8 “unquestionably erro[neous]” exclusion of bias evidence based on passage of time, “a matter for  
 9 the jury to weigh in performing their function of determining the credibility of the witnesses”).

10 In practice, this standard is even lower than it sounds. In *United States v. Ray*, for  
 11 example, the defendant alleged that a key witness was biased because that witness had an on-  
 12 going drug business that would have colored his testimony in favor of the government. *United*  
 13 *States v. Ray*, 731 F.2d 1361, 1363–64 (9th Cir. 1984). The Ninth Circuit reversed the district  
 14 court’s refusal of cross-examination into bias, rejecting government concerns about the  
 15 supposedly insufficient evidence of bias offered by the defendant. *Id.* at 1364–65. As *Ray*  
 16 explained, courts “can require the defendant to offer a threshold level of evidence,” but that level  
 17 is low: namely, whether the allegations of bias “have some grounding in reality.” *Id.* at 1364. In  
 18 *Ray*, that reality-grounding evidence took the form of a plane ticket from Lewiston, Idaho, to  
 19 Boise, Idaho. *Id.* Based on that ticket alone, the defense should have been permitted to ask  
 20 whether the witness traveled on to Florida to purchase cocaine—and it was reversible error to  
 21 reject that questioning. *Id.* at 1364–65. “If the facts are material,” the Court explained, and if there  
 22 is “some grounding in reality,” “the defendant has a right to present [those facts] to the jury.” *Id.*  
 23 at 1364.

24 Here, Mr. Balwani has offered far more than a connecting ticket stub. The evidence of

Dr. Rosendorff's bias is well documented and grounded in reality. Indeed, it is grounded largely in the government's own documents and allegations. Because the jury might reasonably find Dr. Rosendorff's testimony to be affected by that bias, the Court should allow cross-examination aimed at eliciting that bias.

**C. The Government Ignores Bias Arising From Reputational Concerns.**

Nothing in the case law requires criminal exposure or a likelihood of prosecution in order to inquire about bias. Mr. Balwani's motion offered prosecutorial pressure as just one of the possible sources of witness bias. *See* Dkt. 1401 at 3–5. The government misquotes both the case law and Mr. Balwani's brief, omitting the language underlined below to make it seem like a looming prosecution is some kind of requirement:

**Balwani Motion, Dkt. 1401 at 4–5**

“The probative value of such evidence, however, depends in large measure on some showing that the government was contemplating prosecution, or at least was aware, of the illegality.”

**Government Response, Dkt. 1405 at 6**

Indeed, Defendant's own Motion acknowledges that “[t]he probative value of such evidence [of a witness' bias], depends in large measure on some showing *that the government was contemplating prosecution*[.]”

The case at issue, *United States v. Atherton*, was expressly dealing only with bias arising from past criminal activity—not other reasons to curry favor with the government or other reputational concerns. *See* 936 F.2d 728, 733–34 (2d Cir. 1991). And even then, the government misstates the law. As the Supreme Court's canonical bias case *Abel* makes plain, potential sources of bias include “fear of a party”—like fear of prosecution by the government here—but they also include “the witness' self-interest.” *United States v. Abel*, 469 U.S. 45, 52 (1984).

Here, Dr. Rosendorff has an obvious self-interest in protecting his reputation and in deflecting attention to others, like Mr. Balwani. Unless he testifies that others were to blame, Dr. Rosendorff and his reputation (in the lab industry he is still a part of) could reasonably be

questioned in these circumstances, where four different companies for which he served as lab director were or are all under federal and state scrutiny. At the very least, a jury might reasonably conclude as much. Accordingly, the jury should be permitted to evaluate that possible bias—“not only the *fact* of bias but also ... the *source* and *strength* of [his] bias.” *Id.* at 54.

This also explains why the government is wrong that Dr. Rosendorff’s prior, supposedly consistent deposition testimony should assuage any concerns about bias in his trial testimony. *See* Dkt. 1405 at 7. Although that 2019 testimony predated the Invitae subpoena and uBiome indictment in 2021, it long post-dated the actual events at those labs and the specter of reputational damage to Dr. Rosendorff. Moreover, Dr. Rosendorff’s testimony has been anything but consistent: at the Holmes trial, he gave testimony that was flatly inconsistent with the deposition the government now points to as evidence of his reliability. *See, e.g.*, 10/05/2021 Holmes Trial Tr. at 2644–46. A jury could reasonably reject the government’s consistent-testimony theory; indeed, they could instead conclude that Dr. Rosendorff’s inconsistencies are explained by his bias.

**D. Rules 608 And 403 Pose No Obstacle To Cross-Examination On Bias.**

Federal Rule of Evidence 608 poses no obstacle to inquiring about Dr. Rosendorff’s bias as Mr. Balwani proposes. Mr. Balwani does not seek to offer this bias evidence to establish anything about Dr. Rosendorff’s character or propensities. And as the Supreme Court has expressly held, “[i]t [i]s enough that such evidence could properly be found admissible to show bias”—it need not separately be admissible under Rule 608. *Abel*, 469 U.S. at 56; *accord* Fed. R. Evid. 608 advisory committee notes (excluding “[e]vidence of bias or interest” from scope of rule); *Ray*, 731 F.2d at 1364 (“Rule 608(b) does not bar introduction of evidence to show that the witness is biased.”).

Finally, the motion should be granted notwithstanding any concerns about time,

1 complexity, or confusion. As Mr. Balwani’s motion explained, the proposed cross-examination  
2 can be accomplished in an efficient and focused manner. Dkt. 1401 at 6. And the Ninth Circuit  
3 has repeatedly reminded district courts that “unwarranted fear” about these considerations should  
4 yield to a criminal defendant’s interest in “a full and fair opportunity to question” about bias.  
5 *United States v. Brooke*, 4 F.3d 1480, 1489 (9th Cir. 1993). Juries are “routinely” asked to  
6 deliberate over “exceedingly complex factual and legal issues,” including “evaluating allegations  
7 regarding prior, unrelated incidents” that may bear on the case at hand. *Fowler*, 421 F.3d at 1040.  
8 Given those competencies, time and confusion should pose no obstacle to examination into bias.  
9 *See id.* at 1041 (“Nor were the trial court’s concerns about waste of time, confusion and prejudice  
10 sufficiently well-founded to justify precluding rather than limiting the cross-examination.”). The  
11 government’s appeal to Rule 403 ignores this long line of cases and focuses almost exclusively on  
12 the evidence the *government* “would need to” introduce—not the limited cross-examination  
13 Mr. Balwani proposes. Dkt. 1405 at 8. For example, only the government—not Mr. Balwani—  
14 raises the prospect of “detailed evidence” of the PerkinElmer investigation. *Id.*

15       Mr. Balwani has no interest in “mini-trials.” He simply wants the latitude, mandated by  
16 his Confrontation Clause rights, to examine Dr. Rosendorff regarding the bias created by his  
17 involvement with four different companies that all ended up under federal and state  
18 investigations, as well as his resulting need to deflect blame elsewhere. The precise details of the  
19 non-Theranos investigations are not even the point—it is the mere existence of those  
20 investigations and Dr. Rosendorff’s connection with the companies that really matters.  
21 Mr. Balwani has a Sixth Amendment right to inquire into witness bias. Whether the government  
22 will try to mount a distracting mini-trial in response is a separate matter and can be dealt with  
23 appropriately.  
24

1 **III. CONCLUSION**

2 The Court should grant Mr. Balwani's motion and allow cross-examination of  
3 Dr. Rosendorff about his post-Theranos employment and the related federal regulatory and  
4 criminal inquiries.

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6  
7 DATED: April 18, 2022

Respectfully submitted,

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